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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/075,053
Filing Date: February 13, 2002
Appellant(s): STEVENS, ROBERT C.

Michael E. Hudzinski
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed September 20, 2007 appealing from the Office action mailed July 2, 2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,951,539	Nita et al	9-1999
2003/0109851	Landuyt	6-2003

5,728,065 Follmer et al 3-1998

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 6-11, 24, 26-28, 41, 43, 46-53, 56-61, and 63-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nita et al (U.S. Patent 5,951,539). Nita et al disclose a reinforced catheter having an elongate flexible tubular member (528) defining a lumen of the catheter, a continuous coil reinforcement member (522) carried on the tubular member, a first flexible outer coating (546), and a second flexible outer coating (542). The tubular member has a first end defining a proximal end of the catheter and a second end defining a distal end of the catheter. In lines 9-28 of column 9, Nita et al teach that **the continuous coil reinforcement member extends from the first or proximal end of the catheter and terminates at the second or distal end of the catheter**. In Figure 5, the coil reinforcement member terminates at the second or distal end of the catheter and Nita et al teach that the distal nose tip section may not be present in the embodiment shown in Figure 5 or in the other figures where a distal nose tip section has been shown (see lines 7-11 of column 15). Figure 5 is reproduced on the next page and is labeled to show the continuous coil reinforcement member

extending from the proximal end of the catheter and terminating at the second end of the tubular member.

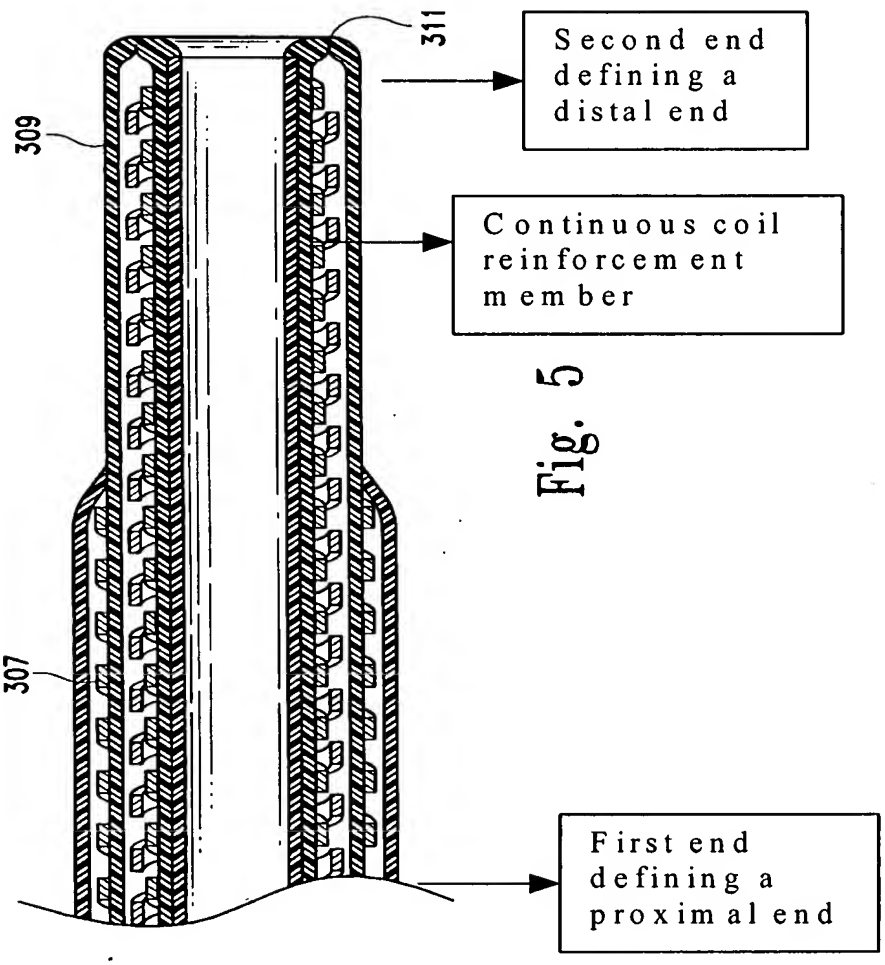

Fig. 5

The catheter in Figure 10 is not specifically described as having a distal nose tip section. However, in the presence or the absence of a distal nose tip section, the catheter of Figure 10 can also be seen as having a continuous coil reinforcement member which extends from the proximal end of the catheter and terminates at the

second or distal end of the catheter. This is due to Figure 10 showing an intermediate section of the catheter which may have a distal section such as those shown in Figures 7, 11, or 12. Therefore, in Figure 10, Nita et al show a first outer coating (546) which covers the coil reinforcement member and tubular member substantially entirely between the proximal end and the distal end of the catheter. A second outer coating (542) covers a first portion of the first outer coating between a transition area of the catheter and the proximal end of the catheter. A second portion of the first outer coating between the first transition area and the distal end of the catheter is uncovered by the second outer coating, thus defining a flexible distal tip. In lines 7-18 of column 16, Nita et al teach that the material of the second outer coating would be chosen such that additional stiffness would be provided to the proximal section of the catheter. Figure 5 is similar to Figure 10 in that it shows a first outer coating (309) and a second outer coating as claimed. In lines 36-56 of column 14, Nita et al disclose the first outer coating at a distal section (246) of the catheter having a Shore hardness of about 40D and at a proximal section (240) of the catheter having a Shore hardness of about 70D. Thus, in the embodiment shown in Figure 10, when the first outer coating (546) has a Shore hardness of 40D, the material of the second outer coating (542) could be chosen to have a Shore hardness of 70D to provide additional stiffness in that proximal section as taught by Nita et al. The tubular member is formed of polytetrafluoroethylene (PFTE) (lines 34-39 of column 10) and the continuous coil reinforcement is a stainless steel wire and defines a helical pattern (lines 9-28 of column 9). In Figure 10, the distal end of the catheter is less than a thickness of the proximal end of the catheter. The first and

second outer coatings may be made of a nylon or an urethane material (lines 19-35 of column 13). As to claim 24, the elongate flexible tubular member has a first end defining a lead end and a second end defining a trailing end and the continuous coil reinforcement member extends from the lead end to the trailing end. In Figure 14F, a continuous outer coating of a first material (572) covers the coil reinforcement member and the tubular member substantially entirely between the lead end and the trailing end. A continuous outer coating of a second material (590) covers the continuous outer coating of the first material (572) substantially entirely between the lead end and the trailing end. In line 65 of column 8 to line 7 of column 9, Nita et al teach that additional layers of polymeric material may be placed between the coil reinforcement member and the outer coating covering the reinforcement member. Additionally, in lines 16-18 of column 13, Nita et al teach that the polyethylene layer (which is the outermost layer or outer coating of the second material) may be left in place which is shown in Figure 14F. As to claim 26, Nita et al teach that the materials for the outer coatings may be chosen to have various values of Shore hardness, including the first material having a Shore hardness of 40D and the second material having a Shore hardness of 70D.

Even though Nita et al teach the first and second outer coatings substantially as claimed and further teach that the material of the second outer coating would be chosen such that additional stiffness would be provided to the proximal section of the catheter, Nita et al are silent on the specifics of the first coating being softer than the second coating. It would have been obvious to one having ordinary skill in the art at the time the invention was made to choose a harder material for the second coating of the

catheter of Nita et al as Nita et al teach **choosing the material of the second coating so that the portion of the catheter with the second coating would be stiffer than the portion without the second coating**. Furthermore, Nita et al teach using **softer coatings on the distal portions of the catheter where more flexibility would be advantageous and using the harder coatings on the proximal sections to provide the desired stiffness to those sections**. As to the specific hardness of the first and outer coatings, the parameter of hardness is deemed a matter of design choice (lacking in any criticality), well within the skill of ordinary artisan, obtained through routine experimentation in determining optimum results.

Claims 1, 3, 6-11, 24, 26-28, 41, 43, 46-53, 56-61, and 63-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nita et al in view of Landuyt (U.S. Patent Application Publication No. 2003/0109851). Nita et al disclose a reinforced catheter having an elongate flexible tubular member (528) defining a lumen of the catheter, a continuous coil reinforcement member (522) carried on the tubular member, a first flexible outer coating (546), and a second flexible outer coating (542). The tubular member has a first end defining a proximal end of the catheter and a second end defining a distal end of the catheter. In lines 9-28 of column 9, Nita et al teach that **the continuous coil reinforcement member extends from the first or proximal end of the catheter and terminates at the second or distal end of the catheter**. In Figure 5, the coil reinforcement member terminates at the second or distal end of the catheter and Nita et al teach that the distal nose tip section may not be present in the

embodiment shown in Figure 5 or in the other figures where a distal nose tip section has been shown (see lines 7-11 of column 15). Figure 5 is reproduced on the next page and is labeled to show the continuous coil reinforcement member extending from the proximal end of the catheter and terminating at the second end of the tubular member.

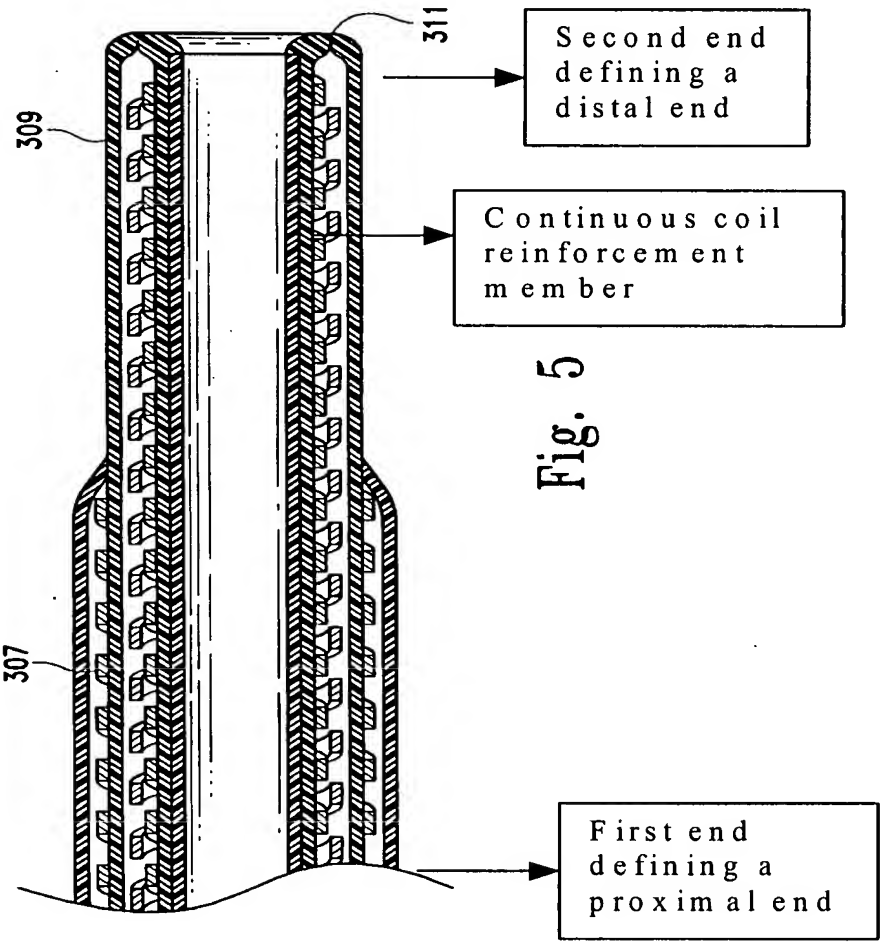

Fig. 5

The catheter in Figure 10 is not specifically described as having a distal nose tip section. However, in the presence or the absence of a distal nose tip section, the

catheter of Figure 10 can also be seen as having a continuous coil reinforcement member which extends from the proximal end of the catheter and terminates at the second or distal end of the catheter. This is due to Figure 10 showing an intermediate section of the catheter which may have a distal section such as those shown in Figures 7, 11, or 12. Therefore, in Figure 10, Nita et al show a first outer coating (546) which covers the coil reinforcement member and tubular member substantially entirely between the proximal end and the distal end of the catheter. A second outer coating (542) covers a first portion of the first outer coating between a transition area of the catheter and the proximal end of the catheter. A second portion of the first outer coating between the first transition area and the distal end of the catheter is uncovered by the second outer coating, thus defining a flexible distal tip. In lines 7-18 of column 16, Nita et al teach that the material of the second outer coating would be chosen such that additional stiffness would be provided to the proximal section of the catheter. Figure 5 is similar to Figure 10 in that it shows a first outer coating (309) and a second outer coating as claimed. In lines 36-56 of column 14, Nita et al disclose the first outer coating at a distal section (246) of the catheter having a Shore hardness of about 40D and at a proximal section (240) of the catheter having a Shore hardness of about 70D. Thus, in the embodiment shown in Figure 10, when the first outer coating (546) has a Shore hardness of 40D, the material of the second outer coating (542) could be chosen to have a Shore hardness of 70D to provide additional stiffness in that proximal section as taught by Nita et al. The tubular member is formed of polytetrafluoroethylene (PFTE) (lines 34-39 of column 10) and the continuous coil reinforcement is a stainless steel wire

and defines a helical pattern (lines 9-28 of column 9). In Figure 10, the distal end of the catheter is less than a thickness of the proximal end of the catheter. The first and second outer coatings may be made of a nylon or an urethane material (lines 19-35 of column 13). As to claim 24, the elongate flexible tubular member has a first end defining a lead end and a second end defining a trailing end and the continuous coil reinforcement member extends from the lead end to the trailing end. In Figure 14F, a continuous outer coating of a first material (572) covers the coil reinforcement member and the tubular member substantially entirely between the lead end and the trailing end. A continuous outer coating of a second material (590) covers the continuous outer coating of the first material (572) substantially entirely between the lead end and the trailing end. In line 65 of column 8 to line 7 of column 9, Nita et al teach that additional layers of polymeric material may be placed between the coil reinforcement member and the outer coating covering the reinforcement member. Additionally, in lines 16-18 of column 13, Nita et al teach that the polyethylene layer (which is the outermost layer or outer coating of the second material) may be left in place which is shown in Figure 14F. As to claim 26, Nita et al teach that the materials for the outer coatings may be chosen to have various values of Shore hardness, including the first material having a Shore hardness of 40D and the second material having a Shore hardness of 70D.

Even though Nita et al teach the first and second outer coatings substantially as claimed and further teach that the material of the second outer coating would be chosen such that additional stiffness would be provided to the proximal section of the catheter, Nita et al are silent on the specifics of the first coating being softer than the second

coating. Landuyt teaches a catheter having a **first coating (11) and a second coating (12) covering a first portion of the first coating between a first transition area of the catheter and the proximal end of the catheter**. As seen in Figure 6, **a second portion (5) of the first coating between the first transition area and the distal end of the catheter is uncovered by the second coating and defines a flexible distal tip**. Landuyt teach that **the first coating (11) is softer than the second coating (12)**. It would have been obvious to one having ordinary skill in the art at the time the invention was made to choose the first coating of Nita et al to be softer than the second coating as taught by Landuyt **as both Nita et al and Landuyt disclose that it is desirable to have the proximal portion of the catheter be more stiffer than the distal portion and Landuyt teach the use of a harder material for the second coating to achieve the desired stiffness while still maintaining a softer distal portion**. As to the specific hardness of the first and outer coatings, the parameter of hardness is deemed a matter of design choice (lacking in any criticality), well within the skill of ordinary artisan, obtained through routine experimentation in determining optimum results.

Claims 4, 5, 44, 45, 54, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nita et al as applied to claims 1, 41, and 52 above, and further in view of Follmer et al (U.S. Patent No. 5,728,065). Nita et al disclose the catheter substantially as claimed. Even though Nita et al teach (in lines 21-31 of column 18) that it is desirable to use a platinum radio-opaque or marker band adjacent the distal end of

the catheter (506 in Figure 8, 534 in Figure 9), Nita et al are silent on the specifics of the marker being disposed on the outer coating. Follmer et al teach a marker band (124) disposed adjacent the distal end of the catcher on the outer coating in the same field of endeavor of reinforced catheters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to place the marker band of Nita et al on the outer coating as taught by Follmer et al as both Nita et al and Follmer et al teach that it is desirable to provide catheters with marker bands and Follmer et al teach that the marker bands can be placed on the outer coating of the catheter.

Claims 4, 5, 44, 45, 54, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nita et al in view of Landuyt as applied to claims 1, 41, and 52 above, and further in view of Follmer et al (U.S. Patent No. 5,728,065). Nita et al disclose the catheter substantially as claimed. Even though Nita et al teach (in lines 21-31 of column 18) that it is desirable to use a platinum radio-opaque or marker band adjacent the distal end of the catheter (506 in Figure 8, 534 in Figure 9), Nita et al are silent on the specifics of the marker being disposed on the outer coating. Follmer et al teach a marker band (124) disposed adjacent the distal end of the catcher on the outer coating in the same field of endeavor of reinforced catheters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to place the marker band of Nita et al on the outer coating as taught by Follmer et al as both Nita et al and Follmer et al teach that it is desirable to provide catheters with marker bands and

Follmer et al teach that the marker bands can be placed on the outer coating of the catheter.

(10) Response to Argument

Applicant's arguments on pages 15-18 with regards to the prior art of Nita et al are not persuasive.

a. Applicant's arguments in line 9 of page 16 to line 7 of page 17 of the Appeal Brief with respect to the specification of Nita et al beginning at line 65 of column 15 are not persuasive. As indicated in lines 9-12 of page 16 of the Appeal Brief, it is Applicant's position that the presence of a bumper tip is specifically included in each of the embodiments of the catheters of Nita et al. However, this argument is not persuasive as in line 65 of column 15 to line 6 of column 16, Nita et al is referring to the embodiment of Figure 9. The disclosure of "When we note that a coil extends to the distal end of the catheter, we intend such a statement nevertheless to include the presence of such a bumper tip (526)" is in reference to Applicant's disclosure in lines 9-28 of column 9 that the coil reinforcement member extends to or terminates at the distal end of the catheter or in lines 53-55 of column 15 that the coil reinforcement member extends distally to a tip or bumper. Nita et al only reference the bumper tip (526) with regards to the embodiments of Figures 8 and 9. If Nita et al intended to include the presence of a bumper tip in each of the embodiments, then the distal most portion of the catheter as seen in Figures 7, 11, and 12 would be considered to have a bumper tip similar to that of Figures 8 and 9 as these are the only embodiments where a bumper tip

has been shown or discussed. However, in the embodiments of Figures 7, 11, and 12, a bumper tip similar to that shown in Figures 8 and 9 is not shown. Even if the distal most portion of the catheter as seen in Figures 7, 11, and 12 is considered to be a bumper tip, **the coil reinforcement member is seen to extend from the proximal end of the catheter and to terminate at the second end of the tubular member where the second end of the tubular member defines a distal end of the catheter** as recited in the claims. Furthermore, the distal most portion of the catheter is part of **the first flexible coating which covers the coil reinforcement member and the tubular member substantially entirely between the proximal end of the catheter and the distal end of the catheter** as recited in the claims. It should be noted that Nita et al disclose the coil reinforcement member extending from the proximal end of the catheter and terminating at the second end of the tubular member where the second end of the tubular member defines a distal end of the catheter in lines 13-17 of column 9, in lines 39-44 of column 15, and in lines 13-23 of column 19.

b. Applicant's arguments in lines 8-14 of page 17 of the Appeal Brief are not persuasive. In lines 9-28 of column 9, Nita et al disclose a continuous coil reinforcement member extending from the proximal end of the catheter and terminating at the distal end of the catheter. The first end of the catheter defines the proximal end and the second end of the catheter defines the distal end. **Therefore, the continuous coil reinforcement member extends from the proximal end of the catheter and terminates at the second end of the catheter.** This is clearly shown in the reproductions of Figure 5 in the preceding pages.

c. Applicant's arguments in line 15 of page 17 to line 6 of page 18 of the Appeal Brief are not persuasive. The interpretation of the disclosure of Nita et al, in lines 7-11 of column 15, clearly indicates that the distal nose tip section may be absent in reference to Figure 5 or other figures. "Use of layers of coil in excess of the preferred dual layer distal-to-proximal layers is a **feature independent of the presence or absence of other features, e.g., the distal nose tip section**" (lines 7-11 of column 15) is interpreted to mean that a distal nose tip section such as that shown in Figure 5 or other figures may be absent. The proper interpretation of this passage is that the use of layers of coil in excess of the preferred dual layer distal-to-proximal layers is a feature that is independent of whether other features such as the distal nose tip section are present or absent. Applicant's interpretation of the use of layers of coil in excess of the preferred dual layer distal-to-proximal layers being a feature independent of the particular nose tip section (311) shown in Figure 5 and independent of any of the other features of the other embodiments of Nita et al is not correct. The Examiner does not agree with Applicant's interpretation of this passage, as Applicant has not given any consideration to the use of the word "absence".

d. As to Applicant's arguments in lines 7-18 of page 18 of the Appeal Brief with regards to Figure 10 of Nita et al, the catheter of claim 10 can be seen as having a continuous coil reinforcement member which extends from the proximal end of the catheter and terminates at the second or distal end of the catheter. In Figure 10, the distal end of the catheter is not shown but the distal ends shown in Figures 7, 11, and 12 are variations of distal ends of the disclosed catheter. Therefore, it can be seen that

a distal end as shown in Figures 7, 11 or 12 where **the coil reinforcement member terminates at the second end of the tubular member would be a reasonable distal end for the catheter shown in Figure 10**.

e. Applicant's arguments in line 19 of page 18 to line 2 of page 19 of the Appeal Brief with regards to Landuyt are not persuasive. **Nita et al disclose the continuous coil reinforcement member extending from one end of the catheter to the other end as stated above**. It has not been indicated by the Examiner that Landuyt teaches or suggests a catheter with the specifics of a continuous coil reinforcement member. Landuyt discloses a catheter having a first coating (11) and a second coating (12) covering a first portion of the first coating between a first transition area of the catheter and the proximal end of the catheter where the second portion (5) of the first coating between the first transition area and the distal end of the catheter is uncovered by the second coating and defines a flexible distal tip. This is similar to the first outer coating and the second outer coating disclosed by Nita et al. Landuyt teach that the first coating (11) is softer than the second coating (12) ([paragraph 0016}) and that the use of a harder material for the second coating achieves the desired stiffness while still maintaining a softer distal portion for the catheter. Therefore, Landuyt clearly teaches that is well known to have the first coating be softer than the second coating.

f. Applicant's arguments in lines 3-19 of page 19 of the Appeal Brief with regards to Follmer et al are not persuasive. **Nita et al disclose the first and second layers of material and the continuous coil reinforcement member extending from one end of the catheter to the other end as stated above**. It has not been indicated by the

Examiner that Follmer et al teach or suggest a catheter with the specifics of first and second layers of material carried on a tubular member and a continuous coil reinforcement member.

g. Applicant's arguments in line 20 of page 19 to line 11 of page 40 of the Appeal Brief are not persuasive. **Nita et al disclose a reinforced catheter having a continuous coil reinforcement member carried on a tubular member where the coil reinforcement member extends from a proximal end of the catheter and terminates at a second end of the tubular member where the second end of the tubular member defines a distal end of the catheter as detailed above**. Also, Nita et al do teach, with respect to Figure 10, that the material of the second coating (542) would be chosen such that it would provide additional stiffness to the proximal section of the catheter. Nita et al do teach using **softer coatings on the more distal portions of the catheter to give the distal portions more flexibility and using harder coatings on the more proximal portions to give the proximal portions more stiffness**. Therefore, a harder material for the second coating would give the proximal section of the catheter more stiffness which Nita et al teach is desirable. Furthermore, in lines 11-16 of column 16, Nita et al specifically disclose that "it is desirable to use materials such as PEBAX (discussed elsewhere)" for the outer layer. Nita et al discuss the use of PEBAX in lines 36-56 of column 14 where Nita et al specifically disclose PEBAX as a preferred material for a coating and also disclose the use of a harder coating on the proximal portion of the catheter and the use of a softer material on the distal portion of the catheter. As to the specific hardness of the first and outer coatings, the parameter

of hardness is deemed a matter of design choice (lacking in any criticality), well within the skill of ordinary artisan, obtained through routine experimentation in determining optimum results. Even so, Nita et al disclose that the first outer coating can have a Shore hardness of about 40D (lines 51-55 of column 14) and that the second outer coating can be chosen to be PEBAX where PEBAX has previously been discussed as having a Shore hardness of about 70D (lines 41-44 of column 14) when it is used in a proximal section of the catheter.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Bhisma Mehta

Conferees:

Robin Evans

Kevin Sirmons

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER